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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,057	02/05/2001	Colin Brown	9052-67	1282
20792 7590 01/16/2009 MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627				
EXAMINER				
WHITE, EVERETT NMN				
ART UNIT		PAPER NUMBER		
1623				
MAIL DATE		DELIVERY MODE		
01/16/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

09/700,057

**Applicant(s)**

BROWN, COLIN

**Examiner**

EVERETT WHITE

**Art Unit**

1623

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on September 29, 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 23, 26-35 and 45-83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23, 26-35 and 45-83 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-144a or PTO-144b)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 29, 2008 has been entered.
2. The amendment affects the instant application accordingly:
  - (A) Claims 1-22, 24, 25 and 36-44 were previously canceled;
  - (B) Comments regarding Office Action have been provided drawn to:
    - (I) 103(a) rejection, which is maintained for the reasons of record.
3. Claims 23, 26-35 and 45-83 are pending in the case.
4. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 103***

5. Claims 23, 26-35 and 45-83 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Dobbie ("Separation of Peritoneal Surfaces Through the Maintenance of an Artificial Ascites as a Preventative of Peritoneal Adhesions" Abstract, from The 4th Peritoneum and Peritoneal Access Meeting, September 16-19, 1997, already of record) in view of Milner (US Patent No. 4,886,789) or Treutner et al (Journal of Surgical Research, "Prevention of Postoperative Adhesions by Singly Intraperitoneal Medication", Vol. 59, pages 764-771 (1995)) for the reasons disclosed on pages 3-5 of the Office Action filed July 16, 2007.
6. Applicant's arguments filed September 29, 2008 have been fully considered but they are not persuasive. Applicants argue against the rejection on the ground that the

Dobbie reference does not make any mention of leaving the Icodextrin solution in the cavity and provides no guidance of how to apply Icodextrin to a body cavity in a method to reduce adhesions. Applicants also argue that one of ordinary skill in the art would not have been motivated by their knowledge of the principles of the dialysis technique, as reiterated in the technique of the Milner patent, to instill fluid into the peritoneal cavity, leave it for a relatively short "dwell" period and replace with fresh solution and to repeat the process daily. This argument is not persuasive since the Dobbie reference refers to the use of continuous ambulatory peritoneal dialysis (CAPD). In CAPD, the dialysis solution, which is the Icodextrin solution in the Dobbie reference, is always inside the "belly" cleansing the blood in a continuous manner. There is no indication in the Dobbie reference that the Icodextrin solution is removed or is used during a short dwell period as argued by Applicants since the Dobbie reference discloses Icodextrin as a non-glycating, long-dwell, peritoneal solution for use post-operatively in patients with a high risk of abdominal adhesions. It is obvious that for the Icodextrin solution to be effective for patients post-operatively of high risk abdominal adhesions, the Icodextrin solution has to be present in the cavity for a sufficient period of time to allow restoration of non-stick surfaces

Applicant arguments in regard to the Treutner et al reference are also noted and have been carefully considered. However, the Treutner et al reference is only cited to show that single intraperitoneal administration of products that are effective in reducing the incidence of post-operative adhesions in the body cavity of a subject over the period of time recited in the instant claims is known in the art.

#### **Arguments Regarding the 1.132 Declaration of Andrew Barrett**

Applicant further provides an argument for secondary consideration to rebut the prima facie case, which has been carefully considered by the Examiner. The secondary consideration forward by Applicant includes evidence of commercial success and licenses of the claimed subject matter provided by the Declaration Under 37 C.F.R. § 1.132 of Andrew Barrett filed September 29, 2008. The declaration includes information about Mr. Barrett as the Director of Business Development and Licensing for Innovata Limited/Vectura Group plc, and cites his involvement with the present technology, and

in particular, the embodiment of the technology provided under the trade name Adept® since the present application was filed. The declaration recites that Mr. Barrett was responsible for the UK launch of Adept® in May 2000 and subsequent licensing of European-wide rights of Adept® to Shire Pharmaceuticals in October 2001 and for the re-licensing of Adept® on a global basis to Baxter Healthcare Corporation in 2006. The declaration further evidenced Adept® as having fulfilled a long-felt surgical need as a safe, efficient, cost-effective, easy to use adhesion reduction agent, and evidenced Adept® as a commercial success. However, in view of the evidence provided in the obviousness type 35 U.S.C. 103 rejection of the claims as being unpatentable over the prior art cited, the evidence of commercial success and licenses of the claimed subject matter as secondary consideration to overcome the rejection is unpersuasive.

Accordingly, the rejection of Claims 23, 26-35 and 45-83 under 35 U.S.C. 103(a) as being unpatentable over the Dobbie reference in view of the Milner patent or the Treutner et al reference is maintained for the reasons of record.

### ***Summary***

7. All the pending claims (Claims 23, 26-35 and 45-83) are rejected.

### ***Examiner's Telephone Number, Fax Number, and Other Information***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is 571-272-0660. The examiner can normally be reached on 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Everett White/

Examiner, Art Unit 1623

/Shaojia Anna Jiang/

Supervisory Patent Examiner, Art Unit 1623